1615 Ch.

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 3-22-05 Signature: Maura A. Gallanber)

Docket No.: ASZD-P01-662

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Birch et al.

Application No.: 10/506748

Filed: September 3, 2004 Art Unit: 1615

For: INDOLE-AMIDE DERIVATIVES AND

THEIR USE AS GLYCOGEN PHOSPHORYLASE INHIBITORS

Examiner: Not Yet Assigned

Confirmation No.: 6588

## **INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A summary/abstract translation of the non-English language references is enclosed.

A copy of each reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this

Application No.: 10/506748 Docket No.: ASZD-P01-662

Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. ASZD-P01-662. A duplicate copy of this paper is enclosed.

Dated: March 22, 2005

Respectfully submitted,

David P. Halstead

Registration No.: 44,735

ROPES & GRAY LLP

One International Place

Boston, Massachusetts 02110-2624

(617) 951-7000

(617) 951-7050 (Fax)

Attorneys/Agents For Applicant

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

illed to respond to a collection of information unless it contains a valid OMB control number.					
Complete if Known					
Application Number	10/506748				
Filing Date	September 3, 2004				
First Named Inventor	Alan Martin Birch				
Art Unit	1615				
Examiner Name	Not Yet Assigned				
Attorney Docket Number	ASZD-P01-662				

	U.S. PATENT DOCUMENTS							
Examiner	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or	Pages, Columns, Lines, Where			
Initials*		Number-Kind Code <sup>2</sup> ( if known)		Applicant of Cited Document	Relevant Passages or Relevant Figures Appear			
	AA	US-2004/0002495-A1	01-01-2004	Philip Sher				
	AB	US-3,706,810	12-19-1972	AMERICAN CYANAMID				
	AC	US-4,599,198	07-08-1986	DENNIS J. HOOVER				
	AD	US-4,668,769	05-26-1987	DENNIS J. HOOVER				
	AE	US-4,720,503	01-19-1988	BRUCE E. WITZEL				
	AF	US-4,751,231	06-14-1988	WASYL HALCZENKO				
	AG	US-4,786,641	11-22-1988	SIEGFRIED GOLDMANN				
	AH	US-4,794,120	12-27-1988	PHILIPPE MANOURY				
	ΑI	US-5,863,903	01-26-1999	KARSTEN LUNDGREN				
	AJ	US-5,998,463	12-07-1999	BERNARD HULIN				

Cite No.1 BA BB BC BD BE	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <i>if known</i> )  WO-00/42213  WO-00/47206  WO-01/05954  WO-01/23347  WO-01/32654	Publication Date MM-DD-YYYY 07-20-2000 08-17-2000 01-25-2001 04-05-2001	Name of Patentee or Applicant of Cited Document  The Research Foundation of State University of New York Novo Nordisk	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т
BB BC BD BE	WO-00/47206 WO-01/05954 WO-01/23347	08-17-2000 01-25-2001	University of New York Novo Nordisk	drawe v	
BC BD BE	WO-01/05954 WO-01/23347	01-25-2001	Novo Nordisk		
BD BE	WO-01/23347		Isia Dharmanauticala Ina		
BE		04-05-2001	Isis Pharmaceuticals, Inc.		
	WO-01/32654	104-03-2001	Novo Nordisk		L
-		05-10-2001	Societe de Conseils de Recherches et D'Applications Scientifiques		
BF	WO-01/52825	07-26-2001	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.		
BG	WO-01/68055	09-20-2001	1		┸
BH	WO-01/68092	09-20-2001	Pfizer Products Inc.		⊥
BI	WO-01/68603	09-20-2001	Bristol-Myers Squibb Co.		$\downarrow$
BJ	WO-01/94300	12-13-2001	Aventis Pharma Deutshland		1
BK	WO-01/96311	12-20-2001	Bristol-Myers Squibb Company		1
BL	WO-01/96347	12-20-2001			l
ВМ	WO-02/080844	10-17-2002			⊥
BN	WO-02/096864	12-05-2002	GmbH		
во	WO-02/098348				$\downarrow$
BP	WO-02/26714				$\downarrow$
BQ	WO-02/34718		Rt.		
BR	WO-03/037864				1
BS	EP-0846464				1
ВТ	EP-0884050	12-16-1998	Novo Nordisk		1
BU	EP-0978279				4
BV	EP-1088824	01-07-2004	Pfizer Products Inc.		1
BW	EP-1125580		Pfizer Products Inc.		1
BX	EP-1134213	09-19-2001	Pfizer Inc.		1
BY	EP-1136071	09-26-2001	Pfizer Products Inc.		1
	BBH BBI BBJ BBK BBL BBM BBN BBN BBP BBQ BBR BBR BBR BBR BBR BBR BBR BBR BBR	BH WO-01/68092 BI WO-01/68603 BJ WO-01/94300 BK WO-01/96311 BL WO-01/96347 BM WO-02/080844 BN WO-02/096864 BO WO-02/096864 BO WO-02/34718 BR WO-03/037864 BS EP-0846464 BT EP-0884050 BU EP-0978279 BV EP-1188824 BW EP-1125580 BX EP-1134213	3H         WO-01/68092         09-20-2001           3I         WO-01/68603         09-20-2001           3J         WO-01/94300         12-13-2001           3K         WO-01/96311         12-20-2001           3L         WO-01/96347         12-20-2001           3M         WO-02/080844         10-17-2002           3N         WO-02/096864         12-05-2002           3O         WO-02/098348         12-12-2002           3P         WO-02/26714         04-04-2002           3Q         WO-02/34718         05-02-2002           3R         WO-03/037864         05-08-2003           3S         EP-0846464         06-10-1998           3T         EP-0884050         12-16-1998           3U         EP-0978279         02-09-2000           3V         EP-1088824         01-07-2004           3W         EP-1134213         09-19-2001	WO-01/68055   O9-20-2001   Pfizer Products Inc.	WO-01/68055   09-20-2001   Pfizer Products Inc.

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

2

Sheet

## **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of

3

Complete if Known				
Application Number	10/506748			
Filing Date	September 3, 2004			
First Named Inventor	Alan Martin Birch			
Art Unit	1615			
Examiner Name	Not Yet Assigned			
Attorney Docket Number	ASZD-P01-662			

BZ	EP-1145717	05-12-2004	Pfizer Products Inc.	
BA1	EP-1149580	02-21-2001	Pfizer Products Inc.	
BB1	EP-1177791	07-27-2001	Pfizer Products Inc.	
BC1	ES-2081747	03-01-1996	Esteve Labor DR	
BD1	DE-4445968	06-27-1996	Bayer AG	
BE1	WO-93/25574	12-23-1993	Pfizer Inc.	
BF1	WO-95/24391	09-14-1995	Novo Nordisk	
BG1	WO-96/39384	12-12-1996	Pfizer, Inc.	
BH1	WO-96/39385	12-12-1996	Pfizer Inc.	
BI1	WO-97/09040	03-13-1997	Novo Nordisk	
BJ1	WO-97/31901	09-04-1997	Mikael Bols	
BK1	WO-97/45425	12-04-1997	Fujisawa Pharmaceutical Co., Ltd.	
BL1	WO-98/27108	06-25-1998	Fuji-Sawa Pharmaceutical Co., Ltd.	
BM1	WO-98/40353	09-17-1998	Novo Nordisk	
BN1	WO-98/50359		Novo Nordisk	
BO1	WO-99/26659	06-03-1999	Pfizer Products Inc.	
BP1	WO-99/36393	07-22-1999	Tanabe Seiyaku Co., Ltd.	
BQ1	JP 2001 089368			
BR1	DD 200740	06-08-1983	Gewald	
BS1	EP 697403	02-21-1996_	Sanofi	
BT1	JP 2001 206856	07-31-2001	Pfizer Prod. Inc.	
BU1	JP 021247565	05-14-1990	Hanawa Netsuden Kinzoku KK	
			Toray Ind. Inc.	
BV1	JP 04179949	06-26-1992		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	CA	Birch, A., et al., "Novel Thienopyrrole Glycogen Phosphorylase Inhibitors: In Vitro SAR and Crystallographic Studies," Poster, AstraZeneca UK, CVGI Research, Mereside, Alderley Park, Macclesfield, Cheshire.				
	СВ	Crochet, R.A., et al., "Synthesis of Substituted Thieno[2,3-b] pyrroles," Vol. 11, 143-150 (April 1974).				
	CC	Freeman, S., et al., "Effect of Glucose on Rat and Human Liver Glycogen Phosphorylasea Activity and Potency of a Glycogen Phosphoylase Inhibitor," Diabetes, 52, Supp., 1470-P, A340.				
	CD	Hartman, G.D., et al., "The Synthesis of 5-Alkylaminomethylthieno[2,3-b]Pyrrole-5-Sulfonamides," Heterocycles, 29(10):1943-1949 (1989).				
	CE	Hoover, D.J., et al., "Indole-2-carboxamide Inhibitors of Human Liver Glycogen Phosphorylase," J. Med. Chem., 41:2934-2938 (1998).				
	CF	Hudson, S., et al., "The effect of a glycogen phosphorylase inhibitor upon muscle fatigue in anaesthetised rats," J. Physiol., 539:52-53 (2002).				
	CG	Jakobsen, P., et al., "Iminosugars: Potential Inhibitors of Liver Glycogen Phosphorylase.,"				

Examiner	Date
Signature	Considered





PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Su	bstitute for form 1449A/B/P	го		Complete if Known		
				Application Number	10/506748	
11	NFORMATIO	N DISC	CLOSURE	Filing Date	September 3, 2004	
S	TATEMENT	BY AF	PPLICANT	First Named Inventor	Alan Martin Birch	
				Art Unit	1615	
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	ASZD-P01-662	

	Bioorganic Med. Chem., 9:733-744 (2001).	
СН	Martin, W.H., et al., "Discovery of a human liver glycogen phosphorylase inhibitor that lowers blood glucose in vivo," PNAS, 95:1776-1781 (Feb. 1998).	
CI	McCormack, J.G., et al., "Pharmacological Approaches to Inhibit Endogenous Glucose Production as a Means of Anti-diabetic Therapy," Curr. Pharmaceutical Design, 7:1451-1474 (2001).	
CJ	Oikonomakos, N.G., et al., "Allosteric inhibition of glycogen phosphorylase alpha by the potential antidiabetic drug 3-isopropyl 4-(2-chlorophenyl)-1,4-dihydro-1-ethyl-2-methyl-pyridine-3,5,6-tricarboxylate," Protein Sci., 8:1930-1945 (1999).	
СК	Rath, V.L. et al., "Activation of Human Liver Glycogen Phosphorylase by Alteration of the Secondary Structure and Packing of the Catalytic Core," Mol. Cell, 6:139-148 (July 2000).	
CL	Rosauer, K.G., et al., "Novel, 3,4-Dihydroquinolin-2(1H)-one Inhibitors of Human Glycogen Phosphorylase a," Bioorganic & Medicinal Chemistry Letters, 13:4385-4388 (2003).	
СМ	Soman, G., et al. "Aromatic Compounds as Allosteric Inhibitors of Glycogen Phosphorylase beta," Biochimica et Biophysica Acta, 358:359-362 (1974).	
CN	Soman, G., et al., "The Nature of the Binding Site for Aromatic Compounds in Glycogen Phosphorylase beta," Biochem. J., 147:369-371 (1975).	
СО	Teague, J., "Mobilisation of Tissue Glycogen Following Inhibition of Glycogen Phosphorylase in fa/fa Rat," Diabetes, 53, Supp. 1, A365, 1521-P	
СР	Treadway, J.L., et al., "Glycogen phosphorlase inhibitors for treatment of type 2 diabetes mellitus," Exp. Opin. Invest. Drugs, 10(3):439-454 (2001).	
CQ	Tumbull, A., et al., "Pharmacological Inhibition of Glycogen Phosphorylase (GP) Lowers Plasma Glucose in Rat Models of Type 2 Diabetes," Diabetes, 52, Supp., 1485-P, A343.	
CR	Venkatarangan, P., et al., "Prediction of Ligand-REceptor Binding Thermodynamics by Free Energy Force Field Three-Dimensional Quantitative Structure-Activity Relationship Analysis: Applications to a Set of Glucose Analogue Inhibitors of Glycogen Phosphorylase," J. Med. Chem., 42:2169-2179 (1999).	
CS	Vertigan, H., "Impact of cell glycogen content on modulation of hepatocyte glucose metabolism by pharmacological agents," Diabetes, 47, Supp., 589, A214.	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
Signature	Considered	

Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.